DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

NDO Surgical, Inc.
Mr. Eric Bannon
Vice President of Regulatory, Clinical
and Quality Assurance
125 High Street, Suite 7
Mansfield, MA 02048

Re: K032820
Trade/Device Name: Endoscopic Plication System, Model # 160-00760
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated (Date on orig SE ltr): October 13, 2003
Received (Date on orig SE ltr): October 14, 2003

Dear Mr. Bannon,

This letter corrects our substantially equivalent letter of October 23, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 1

510(k) Number (if known): K032820

Device Name: Endoscopic Plication System

Indications for Use: The NDO EPS System is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

David R. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032820

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Attachment 6

510(K) SUMMARY

1. SUBMITTER:

NDO Surgical, Inc.
125 High St.
Mansfield, MA 02048
Telephone: 508-337-8881
Fax: 508-337-8882

Contact: Eric Bannon, Vice President, Regulatory, Clinical, QA
Date Prepared: September 8, 2003

2. DEVICE:

Trade Name: NDO Surgical Endoscopic Plication System
Class: II
Classification Name: Endoscope and accessories

3. PREDICATE DEVICE:

NDO Surgical Endoscopic Plication System (K023234)

4. DEVICE DESCRIPTION:

The NDO Surgical Endoscopic Plication System is a device intended to deliver an implant in the stomach near the Gastroesophageal Junction that creates a full thickness plication for the treatment of Gastroesophageal Reflux Disease (GERD). The EPS consists of three components: the Endoscopic Plication Instrument, the Retractor and the Implant Cartridge. The Implant Cartridge and retractor are loaded onto the instrument; this is then passed transorally into the stomach to create the plication. The instrument's shaft, which comes into contact with the patient, is made of polyvinyl chloride coated with parylene. The retractor is made of surgical grade stainless steel, with a polycarbonate sheath. The implant is comprised of two titanium tees, 2.0 polypropylene suture and two ePTFE pledgets. The implant is housed in a disposable cartridge. Once the system has been introduced into the stomach, the retractor is engaged into the gastric mucosa and the tissue is retracted into the arms of the instrument. The arms of the instrument are closed and the implant is deployed, creating the full thickness, serosa-to-serosa plication.

5. INTENDED USE:

The NDO EPS System is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

6. COMPARISON OF CHARACTERISTICS:

The proposed Endoscopic Plication System, is an updated design of the predicate device, it is therefore similar in intended use and function. The design changes made are to further improve patient safety and to allow increased endoscopic visualization of the instrument during the procedure. Additionally, changes were made to the instrument to enable the instrument to be cleaned and processed in a similar manner to that of a standard endoscope.

The indications being requested for the proposed EPS are already cleared for the predicate EPS.

7. PERFORMANCE DATA:

Bench top, In-Vivo simulated use and ex-vivo performance testing were completed in support of the substantial equivalence determination.

The testing demonstrates substantially equivalent performance between the two devices